

IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM INTERNATIONAL)	
GMBH and BOEHRINGER INGELHEIM)	
PHARMACEUTICALS, INC.,)	
)	C.A. No. 05-854-KAJ
Plaintiffs,)	
)	
v.)	
)	
MYLAN PHARMACEUTICALS, INC.,)	
)	
Defendant.)	

**ANSWERING BRIEF IN OPPOSITION TO
MYLAN PHARMACEUTICALS, INC.'S MOTION TO STRIKE
BOEHRINGER'S ALLEGATIONS CONCERNING WILLFUL INFRINGEMENT**

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P. O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
Attorneys for Plaintiffs
Boehringer Ingelheim International GmbH and
Boehringer Ingelheim Pharmaceuticals, Inc.

Of Counsel:

Steven C. Cherny
LATHAM & WATKINS LLP
885 Third Avenue, Suite 1000
New York, NY 10022-4834
(212) 906-1200

Kenneth G. Schuler
Amanda J. Hollis
Joel Neckers
LATHAM & WATKINS LLP
Sears Tower, Suite 5800
Chicago, IL 60606
(312) 876-7700

January 19, 2006

TABLE OF CONTENTS

PRELIMINARY STATEMENT	1
NATURE AND STATE OF PROCEEDINGS.....	1
SUMMARY OF ARGUMENT	1
STATEMENT OF FACTS	2
ARGUMENT	2
A. Mylan Mischaracterizes Applicable Federal Circuit Authority.....	2
B. Boehringer Is Entitled To Discovery Relating To Its Allegations.....	3
CONCLUSION.....	5

TABLE OF AUTHORITIES

<u>Cases</u>	<u>Page(s)</u>
<i>AstraZeneca AB, et al. v. Andrx Pharmaceuticals, LLC, et al.</i> , C.A. No. 04-80 (SLR) (D. Del. Aug. 11, 2004)	3
<i>Glaxo Group Ltd. v. Apotex, Inc.</i> , 376 F.3d 1339 (Fed. Cir. 2004)	1, 2, 3
<i>Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.</i> , 231 F.3d 1339 (Fed. Cir. 2000)	1, 2, 3, 4

STATUTES

35 U.S.C. § 271(e)(4)	3
35 U.S.C. § 285	3

PRELIMINARY STATEMENT

Mylan Pharmaceuticals, Inc. (“Mylan”) has moved to strike the allegations of Plaintiffs Boehringer Ingelheim International GmbH and Boehringer Ingelheim Pharmaceuticals, Inc. (“Plaintiffs” or “Boehringer”) that Mylan has willfully infringed Boehringer’s United States Patent No. 4,886,812 (“the ’812 patent”). Mylan’s arguments are essentially the same as those advanced by Barr Laboratories (“Barr”) in its motion to strike (D.I. 10) in Civil Action No. 05-700 (KAJ). Boehringer herein opposes Mylan’s motion and incorporates by reference, and therefore will not repeat, the arguments from its brief opposing Barr’s motion (D.I. 12). Plaintiffs will restrict their argument to the specific issues raised by Mylan’s brief.

NATURE AND STATE OF PROCEEDINGS

Boehringer filed this lawsuit on December 12, 2005, after Mylan submitted an ANDA seeking approval to sell a generic version of MIRAPEX® and paragraph IV certification with respect to the ’812 patent. Mylan filed an Answer and Counterclaims and its motion to strike on January 4, 2006.

SUMMARY OF ARGUMENT

Mylan’s motion is premised upon a mischaracterization of the Federal Circuit’s decisions in *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004) and *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339 (Fed. Cir. 2000). Mylan incorrectly claims that in *Glaxo*, “[t]he Federal Circuit [. . .] held that [. . .] ***even a baseless Paragraph IV certification*** does not constitute willfulness and, therefore, Plaintiffs’ allegations must fail as a matter of law.”¹ See 376 F.3d 1339; see also Mylan Br. (D.I. 9) at 4. That is not *Glaxo*’s holding. What *Glaxo* held was that “the ***mere filing of an ANDA*** cannot constitute grounds for a

¹ Bold and italic emphasis added throughout unless otherwise noted.

willful infringement determination,” specifically pointing out that there was no Paragraph IV certification in that case. *See* 376 F.3d at 1349, 1351.

Furthermore, Mylan’s argument that the Court should bar discovery related to Plaintiffs’ allegations of willfulness is without basis given that it is undisputed that: (1) Boehringer properly may seek to have this case declared “exceptional”; (2) the Federal Circuit acknowledged in *Yamanouchi* that a finding of willfulness can provide a basis for declaring a case exceptional; and (3) discovery unquestionably is warranted regarding the basis (if any) for Mylan’s paragraph IV certification.

STATEMENT OF FACTS

The relevant facts are set forth in the argument section, as appropriate.

ARGUMENT

A. Mylan Mischaracterizes Applicable Federal Circuit Authority

Boehringer’s Complaint alleges that Mylan willfully infringed the ‘812 patent by filing an ANDA with a paragraph IV certification *and* by acting without a reasonable basis for a good faith belief that it would not be liable for infringing the ‘812 patent. *See* Compl. at ¶ 17. Mylan argues that:

[t]he Federal Circuit in [*Glaxo*] held that under the unique statutory scheme set forth by the Hatch-Waxman amendments, *even a baseless Paragraph IV certification* does not constitute willfulness and, therefore, Plaintiffs’ allegations must fail as a matter of law.

Mylan Br. at 4. *Glaxo*, however, did not so *hold*. *Glaxo* held only that “the mere filing of an ANDA cannot constitute grounds for a willful infringement determination.” *Glaxo*, 376 F.3d at 1349. In fact, the Federal Circuit emphasized that the defendant in *Glaxo* “did not file a paragraph IV certification of any kind, let alone one that made baseless accusations of invalidity

such as that filed in *Yamanouchi*.” *Id.* at 1351 (citing *Yamanouchi*, 231 F.3d 1339, 1346).² Because there was no paragraph IV certification in that case, *Glaxo* could not have *held* that a “baseless” paragraph IV certification does not constitute willful infringement.

B. Boehringer Is Entitled To Discovery Relating To Its Allegations.

Mylan’s corollary argument that discovery related to Boehringer’s allegations of willfulness should be stayed has no basis. The question whether Mylan’s paragraph IV certification was “baseless” will be considered whether willfulness is a “stand alone” claim or as part of the exceptional case analysis. Although the parties dispute whether willfulness may be considered as a “stand alone” claim, neither party disputes that discovery is appropriate regarding whether Mylan had an “adequate foundation” to file its ANDA and paragraph IV certification as a component of the exceptional case analysis -- Mylan merely wishes to stay discovery regarding whether it had an adequate foundation for its certification. *See Yamanouchi*, 231 F.3d 1339, 1346-47; Mylan Br. at 5. In *Yamanouchi*, the parties took discovery regarding defendant’s basis for its certifications and participated in a full bench trial, and the Federal Circuit did not state that the discovery should not have taken place. In fact, the Court expressly stated that “willful infringement” is a form of misconduct that can lead to a case being declared exceptional:

section 271(e)(4) authorizes fee awards for paragraph (2) infringement in accordance with the standards for section 285 exceptional cases. This court, in turn, has recognized many varieties of misconduct that make a case exceptional for a fee award. These forms of misconduct include

² Mylan cites several district court cases in support of its position that a baseless ANDA and paragraph IV certification cannot support a finding of willful infringement. *See* Mylan Br. at 6. However, as discussed in Boehringer’s opposition to Barr’s motion (D.I. 12), these cases, along with Judge Robinson’s decision to permit discovery on willfulness in *AstraZeneca AB, et al. v. Andrx Pharmaceuticals, LLC, et al.*, C.A. No. 04-80 (SLR) (D. Del. Aug. 11, 2004) (Ex. A to Plaintiffs Br. in Response to Barr’s Motion to Strike), only highlight an ambiguity in the law.

willful infringement, inequitable conduct before the PTO, offensive litigation tactics, vexatious or unjustified litigation, or frivolous filings. . .

231 F.3d at 1346-47 (citations omitted). In fact, the defendant's bad faith submission of its paragraph IV certification formed part of the basis for the holding that the case was exceptional in *Yamanouchi*. See 231 F.3d at 1347 (“[defendant’s] *misconduct in filing a wholly unjustified ANDA certification* and misconduct during the litigation that followed *warranted the district court’s finding that this case was exceptional.*”). Although the Federal Circuit stated that the district court need not have determined that defendant’s conduct amounted to willfulness, the Federal Circuit relied on the *same evidence* in holding that defendant’s ANDA filing was “without adequate foundation and speculative at best” and in finding the case exceptional and affirming the award of attorneys’ fees. *Id.* at 1347. Thus, discovery regarding whether Mylan had an “adequate foundation” to file its paragraph IV certification (or whether that filing was “baseless”) will be a part of this case regardless of whether willfulness is considered as a “stand alone” claim or simply a component of the exceptional case analysis.

Mylan argues, as did Barr, that it should be able to submit a paragraph IV certification *based on absolutely nothing* to provoke a challenge to a duly issued United States Patent with the hope that such conduct will never be discovered. Mylan’s attempt to marginalize the inquiry into the “basis” for its paragraph IV certification is inconsistent with the Federal Circuit’s statement that an infringer under the Hatch-Waxman Act must show “due care” before infringing:

Specifically, a paragraph IV filing requires “a certification, in the opinion of the applicant and to the best of his knowledge, [that] each patent . . . for which the applicant is seeking approval . . . is invalid.” The Hatch-Waxman Act thus imposes a duty of care on an ANDA certifier. Thus, a case initiated by a paragraph (2) filing, like any other form of infringement litigation, may become exceptional if the ANDA filer makes baseless certifications.

231 F.3d at 1347 (citations omitted; original emphasis).

With no damages at issue, Mylan has little incentive to ensure that its paragraph IV certification has an adequate foundation if Boehringer cannot take discovery relating to the basis (if any) for that certification. Mylan's certification could be nothing more than a shot in the dark, a calculated risk in an attempt to obtain approval to sell a highly profitable and successful drug that it did not develop. Mylan seeks to defer the question of whether its paragraph IV certification is baseless, with the hope that it will never see the light of day and that if Boehringer prevails on the merits, it will not choose to take the discovery for the purposes of obtaining its attorneys fees after Mylan is permanently enjoined.

CONCLUSION

For the foregoing reasons, the Court should deny Mylan's Motion to Strike.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld (#1014)

Jack B. Blumenfeld (#1014)

Maryellen Noreika (#3208)

1201 North Market Street

P. O. Box 1347

Wilmington, DE 19899-1347

(302) 658-9200

jblumenfeld@mnat.com

Attorneys for Plaintiffs

Boehringer Ingelheim International GmbH

and Boehringer Ingelheim

Pharmaceuticals, Inc.

Of Counsel:

Steven C. Cherny
LATHAM & WATKINS LLP
885 Third Avenue, Suite 1000
New York, NY 10022-4834
(212) 906-1200

Kenneth G. Schuler
Amanda J. Hollis
Joel S. Neckers
LATHAM & WATKINS LLP
Sears Tower, Suite 5800
Chicago, IL 60606
(312) 876-7700

January 19, 2006

CERTIFICATE OF SERVICE

I, Jack B. Blumenfeld, hereby certify that on January 19, 2006, I caused to be electronically filed Answering Brief in Opposition to Mylan Pharmaceuticals, Inc.'s Motion to Strike Boehringer's Allegations Concerning Willful Infringement with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer
Morris, James, Hitchens & Williams

and that I caused copies to be served upon the following in the manner indicated:

BY HAND

Mary B. Matterer
Morris, James, Hitchens & Williams
222 Delaware Avenue
P.O. Box 2306
Wilmington, DE 19899

BY FEDERAL EXPRESS

Shannon M. Bloodworth
Heller Ehrman LLP
1717 Rhode Island Avenue, NW
Washington, DC 20036

/s/ Jack B. Blumenfeld (#1014)

Morris, Nichols, Arsht & Tunnell LLP
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld @mnat.com